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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/535,341	06/09/2006	Sung Youb Jung	Q115525	7156

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EXAMINER	
DAHLE, CHUN WU	

ART UNIT	PAPER NUMBER
1644	

NOTIFICATION DATE	DELIVERY MODE
02/28/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/535,341	JUNG ET AL.	
	Examiner	Art Unit	
	CHUN DAHLE	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 October 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13 and 16* is/are pending in the application.

4a) Of the above claim(s) *8-12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,13 and 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/08/2010 and 01/06/2011*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission, filed on October 26, 2010, has been entered.

2. Applicant's amendment to the claims, filed on October 26, 2010, is entered.
Claims 14 and 15 have been canceled.
Claim 16 has been added.

Claims 1-13 and 16 are pending.

Claims 8-12 stand withdrawn from further consideration by the Examiner, under 37 C.F.R. 1.142(b), as being drawn to nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on February 15, 2008.

Claims 1-7, 13, and claim 16 are currently under consideration as they read on the elected invention of an Fc fragment and SEQ ID NO:8.

3. This Office Action will be in response to applicant's arguments, filed on October 26, 2010.

The rejections of record can be found in the previous Office Action, mailed on June 10, 2008, March 4, 2009, October 27, 2009, and May 27, 2010.

4. Applicant's submission, of computer readable form of the sequence listing and paper copy thereof, and the statement that the content of the paper and computer readable copies are the same, filed on July 27, 2010, is entered.

5. In view of timely filed terminal disclaimers in compliance with 37 CFR 1.321(c) or 1.321(d), the prior provisional obviousness type double patenting rejection against USSNs 10/535,231 and 10/535,232 have been withdrawn.

Given the abandonment of USSNs 11/747,153 and 11/947,697, the prior ODP rejections have been withdrawn.

6. In view of applicant's amendment to the claims, only following rejections have been set forth herein.

7. Claim 16 is objected to for following informality:

The word "polyethtylene" on line 3 of the claim 16 should be "polyethylene".

Appropriate correction is required.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claim 16 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The phrase "wherein the non-peptide linker is a polyethylene glycol having a molecular weight of 3.4 kDa-10 kDa" in newly added claim 16 is not supported by the original disclosure or claim as filed.

Applicant's amendment, filed on October 26, 2010, directs to support to original claims 1 and 15, Examples 5 and 11 on pages 52 and 59 of the specification as filed, and asserts that no new matter has been added.

However, the specification as filed does not provide sufficient written description of the above-mentioned "limitation". The specification does not provide sufficient support for the range of the molecular weight for the polyethylene glycol (PEG) as claimed. The specification only discloses PEG having molecular weight of 3.4 kDa and 10 kDa (e.g. see Examples 5 and 11 on pages of 52 and 59 of the specification); the instant claim 16 now recites PEG having a molecular weight of 3.4 kDa-10 kDa, which was not clearly disclosed in the specification. Therefore, the claim represents a departure from the specification and claims originally filed. Applicant's generic disclosure of PEG and limited species of PEG having molecular weight of 3.4 or 10 kDa do not provide sufficient direction and guidance to the features currently claimed.

Such limitation recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant is required to cancel the new matter in the response to this Office Action.

Alternatively, applicant is invited to provide sufficient written support for the "limitations" indicated above. See MPEP 714.02, 2163.05-06 and 2173.05 (i).

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1-7, 13, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kostenuik et al. (US Patent 6,756,480, reference of record) in view of Bentz et al. (J. Biomed. Mat. Res. 39(4):539-548, 1998, reference on IDS) and Mohamed et al. (US 2006/0153839).

Kostenuik et al. claim:

"1. A polypeptide comprising a parathyroid hormone (PTH) peptide and a Fc domain, wherein said Fc domain is covalently attached to the C-terminus of said PTH peptide.

2. The polypeptide of claim 1 further comprising a linker attaching said Fc domain to said PTH peptide."

On columns 33-34, Kostenuik et al. define that a linker can be PEG.

Kostenuik et al. teach parathyroid hormone peptide (PHP) covalently linked to an Fc domain via a linker (e.g. see claims 1-3). Kastenuik et al. further teach that said linker can be non-peptide linker such as PEG linkers about 10 KDa or dextran (e.g. see Linkers defined on columns 33-34). Further, Kastenuik et al. teach that said Fc domain can be human IgG1, 2, 3, or 4 and aglycosylated (e.g. see columns 8-9 and 31-32). Furthermore, Kastenuik et al. teach pharmaceutical composition comprising said PHP covalently linked to an Fc (e.g. columns 39-40). Given that the recited SEQ ID NO:8 is the amino acid sequence of the Fc region of human mature IgG4, the prior art Fc region from human IgG4 would read onto the instant claim 7 encompassing SEQ ID NO:8.

The reference teachings differ from the claimed invention by not exemplifying Fc-non-peptide linker-PHP.

However, methods of covalently linking proteins with non-peptide linkers such as polyethylene glycol were well known in the art at the time the invention was made. For example, Bentz et al. teach that activated polyethylene glycol (PEG) is a biocompatible hydrophilic polymer that has been successfully used in modifying enzymes and growth factors; PEG-attached proteins are more stable and usually remain highly active (e.g. see right column on page 539). Further, Bentz et al. teach that TGF-β2 covalently linked to collagen via difunctional PEG results in significantly more consistent, stronger, and longer-lasting in vivo effect associated with TGF-β2 and that the difuncitonal PEG is useful for delivery of other peptide growth factors (e.g. see page 547). Mohamed et al. teach methods of producing bispecific proteins molecules using PEG linkers having formula of X-PEG-Y (X and Y stands for different proteins) (e.g. see pages 15-16). It would thus be obvious to one of skill in the art at the time the invention was made to combine the teachings of the reference to produce an Fc linked drugs (e.g. PHP) via non-peptide linkers such as PEG because PHP covalently linked to an Fc via PEG would be expected to have the advantages including longer half life. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference

claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 1-7, 13, and 16 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-25 of copending USSN 11/910,962 for the reasons of record.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments, filed on October 26, 2010, have been fully considered but have not been found persuasive.

Applicant argues that the copending USSN 11/910,962 is filed later than the instant application. Thus, applicant asserts that according to MPEP 804, the provisional ODP rejection should be withdrawn permitting the instant application to be issued as a Patent.

This is not found persuasive because the ODP rejection is not the only rejections remaining in the instant application (see rejections set forth above in this Office Action). Given that no terminal disclaimer signed by the assignee and fully complied with 37 CFR 3.73(b) was filed, the provisional rejection on the ground of nonstatutory obviousness-type double patenting is maintained.

14. No claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chun Dahle whose telephone number is 571-272-8142. The examiner can normally be reached on 8:30-5:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Ram Shukla can be reached 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Chun Dahle/
Primary Examiner, Art Unit 1644